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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/011,977	06/15/98	AMMON H	015200-054

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1623	6

DATE MAILED: 09/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/011,977	Ammon et al.
Examiner	**Group Art Unit**
Howard Owens	1623

☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Arguments

The following is in response to the amendment filed 6/2/99:

An action on the merits of claims 1-8 is contained herein below.

Abstract

As cited in the office action mailed 2/17/99, this application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

Specification

Objection to the specification with regards to the form has been overcome through applicant's amendment.

35 USC § 112

The rejection of claims 10 and 11 under 35 U.S.C. 112(1)is maintained.

Claims 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for combating pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis or rheumatoid arthritis, does not reasonably provide enablement for the prevention of tumors and neoplasms as broadly asserted. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 11 is drawn to a method of preventing and/or combating pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis,rheumatoid arthritis tumors and neoplasms in a mammal by administering an effective amount of boswellic acid, a

physiological acceptable salt, a derivative, a salt of the derivative or a plant preparation containing boswellic acid.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breadth of the claims and the
8) level of skill in the art.

Quantity of experimentation necessary, Amount of guidance presented, Presence or absence of working examples

Applicant provides guidance for the treatment of symptoms associated with the disease states of pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis or rheumatoid arthritis through. Applicant incorporates by reference evidence that given that plasmin may activate growth factors which can stimulate the reproduction of tumors, inhibition of plasmin activity may possibly inhibit the growth and metastatic spread of many kinds of cancer. Inhibition of plasmin activity however, would not guarantee a prevention of neoplasms. Given that these neoplasms or tumors are a cellular malignancy whose unique characteristic - loss of normal controls - results in unregulated growth, lack of differentiation, and ability to invade local tissues and metastasize.

Applicant however provides no guidance or sets forth sufficient examples to substantiate the prevention of a neoplasm given that the art does not support conclusively the prevention of a broad class of neoplasms; furthermore, for any assertion to neoplasms or tumors broadly, there should be an adequate written description which teaches how to use the instant active ingredient(s) in methods which substantiate that the claimed therapeutic compounds have efficacy as broadly asserted for preventing neoplasms.

Applicant's references to a mammalian organism in need is seen to include all mammalian organisms, including healthy mammalian organisms. All mammalian organisms are in need of preventing neoplasms, pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis and rheumatoid arthritis. No support is given for administering the active agent to a healthy mammalian organism and preventing onset of specific disease states, specifically neoplasms, pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis and rheumatoid arthritis.

State of the Prior Art

While the prior art is replete with examples of anticancer activity associated with boswellic acid or pentacyclic triterpenoid compounds, the art has not established a consistent therapeutic system which would enable prevention of a broad class of neoplasms.

Breadth of the Claims

Claim 11 is drawn to a method of preventing and/or combating pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis,rheumatoid arthritis tumors and neoplasms in a mammal by administering an effective amount of boswellic acid, a physiological acceptable salt, a derivative, a salt of the derivative or a plant preparation containing boswellic acid. Note applicant has broadly asserted the prevention of neoplasms and tumors.

Level of Skill in the Art

The relative skill in the art of formulating and determining methods for antineoplastic compounds, treatment of humans and mammals with neoplasms, is that of a Ph.D. and or M.D.

Although the art has established the usefulness of boswellic acid or pentacyclic triterpenoid compounds in the treatment of cancer, there is not seen adequate support for the prevention of a broad spectrum of neoplasms or tumors by these compounds or compositions as broadly asserted; thus claims drawn to the prevention of these neoplasms as broadly asserted should set forth therapeutic dosages or ratios in combination with other therapeutic agents. The specification also fails to teach how to use the instantly claimed compounds or compositions in the treatment of neoplasms singularly or in combination with other well known, art recognized means of treatment such as the use of additional chemotherapeutic agents simultaneously or in tandem which

would provide prevention of a neoplasm or tumor in a human or mammal.

Applicant claims that claims 10 and 11 are drawn to a method or preventing growth, however the claim clearly states "a method for preventing and/or combatting diseases....". Again, although the art has established the usefulness of boswellic acid or pentacyclic triterpenoid compounds in the treatment of cancer, there is not seen adequate support for the prevention of a broad spectrum of neoplasms or tumors by these compounds or compositions as broadly asserted; thus claims drawn to the prevention of these neoplasms as broadly asserted should set forth therapeutic dosages or ratios in combination with other therapeutic agents. The specification also fails to teach how to use the instantly claimed compounds or compositions in the treatment of neoplasms singularly or in combination with other well known, art recognized means of treatment such as the use of additional chemotherapeutic agents simultaneously or in tandem which would provide prevention of a neoplasm or tumor in a human or mammal.

35 U.S.C. 112(2)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. In claim 10, use of the terms "plant preparation" do not clearly set forth what applicant intends. In the absence of a process for the preparation of plant material and given the variety of methods available for processing plant material as well applicant should particularly point out and distinctly claim what is intended by the terms "plant preparation".

The rejection of claim 16 under 35 U.S.C. 112(2)is maintained. As, limitations in the specification are not read into the claims, applicant particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substance" in claim 16 renders the instant claim indefinite as applicant has failed to set forth with distinction what substance is claimed in conjunction with the boswellic acid, given the multitude of compounds and extracts that could be encompassed by the indiscriminate term "substance". Applicant's assertion that one of skill in the art would know what "chemically pure" means does not remedy the fact that levels of purity commonly differ in this art based on the use. Therefore use of this relative terminology should be accompanied by subject matter which provides a standard for ascertaining the requisite degree of purity.

35 USC § 103

The rejection of claims 10 -16 under 35 U.S.C. 103(a) is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens

Group 1623

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600